K130404

JUL 5 2013

1430 Waukegan Road
McGraw Park, IL 60085

www.cardinal.com

510(k) SUMMARY
Surgical Drape

Manufacturer:	Cardinal Health 200, LLC 1430 Waukegan Road McGaw Park, IL 60085
Regulatory Affairs Contact:	Lavenia Ford 1430 Waukegan Road McGaw Park, IL 60085
Telephone Number:	(847) 887-3323
Date summary Prepared:	April 17, 2013
Trade Name:	Tiburon® surgical drape
Classification:	Class II per 21 CFR § 878.4370
Classification Name:	Surgical Drape
Common Name:	Surgical Drape
Product Code:	KKX
Predicate Device:	K031287 3M Health Care Steri-Drape™ Fabric Surgical Drape

Description:

The Cardinal Health Tiburon® surgical drapes described in this submission are single use disposable sheets designed to provide an absorbent sterile barrier during surgical procedures. The drapes cover the patient and are made of absorbent nonwoven fabric backed with a protective film that stops fluid strike-through. The drapes are provided in various sizes and shapes to meet the requirements of the surgical procedure. The sterile product will be sold as an individually ethylene oxide sterilized wrapped drape that is placed in a polyolefin – based vented pouch and heat sealed prior to sterilization and are intended for external use only.

These drapes are comprised of a fabric that is an blue absorbent polyolefin spun melt nonwoven fabric adhesively bonded to a polyolefin blue film.

Cardinal Health Tiburon® surgical drapes meet the Level 4 requirements of the AAMI Liquid Barrier Classifications.

This submission covers ten different models of Cardinal Health surgical drapes in **Table 1.** The catalog numbers listed in this submission are representative of all drape models. All models utilize the same material technology.

Extensive performance testing has been completed on the Cardinal Health Tiburon® surgical drape. The physical properties of surgical drape have been characterized after sterilization. Completion of the performance tests demonstrated that the surgical drape provides an adequate sterile barrier after sterilization.

Indications for Use:

Cardinal Health Tiburon® surgical drapes are devices made of natural or synthetic materials intended to be used as a protective patient covering to isolate a site of surgical incision from microbial and other contamination. The drape is sterilized using ethylene oxide and is intended for single external use only.

This drape is classified as Level 4 per AAMI Standard PB70 Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health-care Facilities.

Table # 1 – Product Catalog numbers

	Indications for Use Catalog Number List	**Catalog Number**	**SF = spunbond/film PE= Polyethylene**
	Product Description		**Drape Materials**
No.		**Sterile**	
1	Three-quarter Drape Sheet	9349	SF base panel
2	Laparotomy Drape	29410	SF base panel with SF reinforcement
3	General Endoscopy Drape	9458	SF base panel with SF reinforcement
4	Cardiovascular Split Drape II	9158	SF base panel with SF reinforcement
5	Arthroscopy Drape for Dropped Leg Procedures	9414	SF base panel with SF reinforcement
6	Arthroscopy Hip Drape with Pouch	29439	SF base panel with SF reinforcement
7	Beach Chair Shoulder Drape	29369	SF base panel with PE pouch and elastomeric film
8	Pediatric Drape	29492	SF base panel with SF reinforcement
9	LAVH Drape	29474	SF base panel with SF reinforcement
10	Split Sheet Drape	29436	SF base panel with SF reinforcement

Substantial Equivalence

The Cardinal Health Tiburon® surgical drapes are substantially equivalent to the predicate device, 3M Health Care Steri-Drape™ Fabric Surgical Drape. Both devices have the same intended use, similar material composition, similar film and nonwoven components, same sterilization modality (ethylene oxide) and compatibility with that modality, similar drape configurations/dimensions, similar labeling content, and comparable physical performance attributes (including strength, basis weight, flammability).

Table #2 – Overall Comparison of Predicate and Proposed Device

Element of Comparison	**PREDICATE** **3M Steri-Drape™ Surgical Drape (K031287)**	**PROPOSED** **Cardinal Health Tiburon® surgical drape**	**Comparison to Predicate**
Indications for Use	3M Steri-Drape™ Surgical Fabric Drapes are used to create a sterile field for a surgical procedure. They are provided sterile using ethylene oxide or gamma radiation and intended for external use only. 3M Steri-Drape™ non-sterile fabric drapes are provided to other manufacturers for further processing using ethylene oxide. 3M provides information on compatibility with ethylene oxide processing.	Cardinal Health Tiburon® surgical drapes are devices made of natural or synthetic materials intended to be used as a protective patient covering to isolate a site of surgical incision from microbial and other contamination. The drape is sterile using ethylene oxide and is intended for single external use only. These drapes are classified as Level 4 per AAMI Standard PB70 liquid barrier performance and classification of protective apparel and drapes intended for use in health-care facilities.	Substantially Equivalent
Material Composition	Drape fabric, with a blue absorbent nonwoven on top and a blue film on the underside.	Drape fabric, with a blue absorbent nonwoven on top and a blue film on the underside.	Substantially Equivalent
Lamination	Unknown	Adhesive	Unknown
Sterilization Modality	Ethylene Oxide or Gamma Irradiation	Ethylene Oxide	Substantially Equivalent
Configurations/ Dimensions	Various sizes and shapes	Various sizes and shapes	Substantially Equivalent
Material Compatibility with Ethylene Oxide	Compatible	Compatible	Substantially Equivalent
Biocompatibility	Unknown	Non-cytotoxic Non-sensitizing Non-irritating	Unknown
Labeling	Label content: Catalog number drape description visible Drape Dimensions and drawing on label Lot number visible No barrier AAMI level listed Site of manufacturing listed Labeled as sterile Labeled as single use only	Label content: Catalog number drape description visible Drape Dimensions and drawing on label Lot number visible AAMI level listed Company address listed Labeled as sterile Labeled as single use only	Substantially Equivalent
Barrier Properties	Unknown	AAMI PB70 Barrier Level 4	Unknown

Summary of Testing

Cardinal Health Tiburon® surgical drapes performance has been tested in accordance with the applicable requirements recommended in the FDA's Guidance on Premarket Notification [510(k)] Submissions for Surgical Gowns and Surgical Drapes, Infection Control Devices Branch Division of General and Restorative Devices, August, 1993 in this submission. In addition to performance testing in accordance with industry recognized standards; these drapes were evaluated according to ISO 10993 and are considered toxicologically acceptable for its intended use. Cardinal Health Tiburon® surgical drapes were tested in compliance with the requirements of Level 4 liquid barrier performance of AAMI Standard PB70 liquid barrier performance and classification of protective apparel and drapes intended for use in health-care facilities.

Conclusions:

Based on the results of the biocompatibility and physical performance testing, Cardinal Health Tiburon® surgical drape is safe for its intended use. The Cardinal Health Tiburon® surgical drape is substantially equivalent to the predicate device, 3M Health Care Steri-Drape™ Fabric Drape, in terms of general intended use, physical performance testing, material composition, sterilization modality and compatibility, drape configurations/dimensions, and labeling, and safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

July 5, 2013

Cardinal Health 200, LLC
Ms. Lavenia Ford
Regulatory Affairs Manager
1430 Waukegan Road
MCGAW PARK, IL 60085-6786

Re: K130404
Trade/Device Name: Cardinal Health Tiburon® Surgical Drape
Regulation Number: 21 CFR 878.4370
Regulation Name: Surgical drape
Regulatory Class: II
Product Code: KKX
Dated: April 8, 2013
Received: April 10, 2013

Dear Ms. Ford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

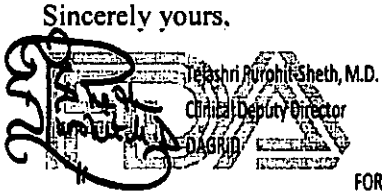
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



FOR

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital
Respiratory, Infection Control and
Dental Device
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

CardinalHealth

Indications for Use

510(k) Number (if known): K130404

Device Name: Cardinal Health Tiburon® surgical drape

Cardinal Health Tiburon® surgical drapes are devices made of natural or synthetic materials intended to be used as a protective patient covering to isolate a site of surgical incision from microbial and other contamination. The drape is sterilized using ethylene oxide and is intended for single external use only.

This drape is classified as Level 4 per AAMI Standard PB70 liquid barrier performance and classification of protective apparel and drapes intended for use in health-care facilities.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

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Elizabeth F. Claverie -S Concurrence of CDRH, Office of Devices Evaluation (ODE)
2013.06.28 22:08:05 -04'00'

Division Sign-Off
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) K130404

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